UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF NEW YORK

SAEED A. BAJWA, MD,

Plaintiff,

v.

THOMAS E. PRICE, MD, Secretary of the United States Department of Health and Human Services,

Defendant.

CIVIL ACTION NO. 3:17-cv-792 (GTS/DEP)

VERIFIED COMPLAINT

BACKGROUND

- 1. In this action, Plaintiff Saeed A. Bajwa, M.D. ("Dr. Bajwa") seeks relief from the unlawful revocation of his Medicare billing privileges by the United States Department of Health and Human Services, acting through the Centers for Medicaid & Medicare Services ("CMS"), in October 2015. The Court should reverse CMS' revocation determination because (1) the statute and regulation under which it was effected are Constitutionally invalid, (2) the manner in which it was effected deprived Dr. Bajwa of Constitutional Due Process, and (3) CMS' revocation of Dr. Bajwa's Medicare billing privileges—and its decision to impose a 3-year re-enrollment bar—were arbitrary and capricious and contrary to law.
- 2. National Government Services ("NGS"), a contractor acting on behalf of CMS, revoked Dr. Bajwa's Medicare billing privileges based upon impermissible retroactive application of a regulation amended in 2014 to Dr. Bajwa's conduct that occurred long before that date. Dr. Bajwa had no pre-revocation notice or opportunity to be heard, and CMS revoked Dr. Bajwa's privileges based upon a statute and regulation that fails to give medical providers Constitutionally sufficient "fair notice" of conduct that CMS may deem a basis for revocation.

Moreover, CMS' conduct in the retroactive application of the rule, and in its determination to revoke Dr. Bajwa's Medicare billing privileges was impermissibly arbitrary and capricious, an abuse of discretion, and otherwise contrary to law.

PARTIES

- 3. Plaintiff Saeed A. Bajwa, MD is a medical doctor specializing in neurosurgery licensed to practice medicine in the State of New York. Neurosurgery is the medical specialty concerned with the prevention, diagnosis, treatment, and rehabilitation of disorders which affect any portion of the nervous system including the brain, spinal cord, peripheral nerves, and extracranial cerebrovascular system. The conditions that neurosurgeons treat include diseases, such as cancerous tumors, as well as strokes and traumatic injuries. Dr. Bajwa is frequently called upon to perform surgeries to save the life or prevent permanent, debilitating injuries or blindness.
- 4. Prior to CMS' revocation decision, Dr. Bajwa was a partner in the Southern New York Neurosurgical Group PC ("SNY"), a private neurosurgery physician group organized as a professional corporation under the laws of the State of New York, with offices located at 46 Harrison Street, Johnson City, New York. Dr. Bajwa owned SNY in equal parts with his two partners, Dr. Khalid Sethi and Dr. Daniel Galyon. SNY's Medicare billing privileges were also initially revoked based on Dr. Bajwa's ownership of more than 5 percent of SNY, and thereafter Dr. Sethi and Dr. Galyon were unable to bill Medicare for services they provided until after they forced Dr. Bajwa out of the SNY partnership.
- 5. Defendant Thomas E. Price, MD is the Secretary of the United States Department of Health and Human Services ("HHS"), an agency of the Executive Branch of the United States government, and is named as a party defendant in this action solely in his official capacity. The

Centers for Medicare & Medicaid Services (CMS) is the operating component of HHS responsible for the administration of Medicare.

JURISDICTION AND VENUE

- 6. This Court has jurisdiction over the subject matter of this action pursuant to 42 U.S.C. § 405(g).
- 7. Dr. Bajwa has satisfied the requirement of presentment of his claim to the Secretary by requesting review of the revocation by an administrative law judge (the "ALJ"), as well as review of the ALJ's decision by the Departmental Appeals Board (the "DAB").
- 8. Dr. Bajwa has exhausted his administrative remedies in that he sought and received review of the revocation by an administrative law judge, as well as review of the ALJ's decision by the DAB. Dr. Bajwa received a final adverse decision from the DAB on June 22, 2017.
- 9. Venue in this judicial district is proper under 42 U.S.C. § 405(g) because Dr. Bajwa resides in this judicial district and has his principal place of business in this judicial district.

FACTS

Dr. Bajwa's Conviction

10. In November 2013, based on allegations later found to be untrue, Dr. Bajwa was indicted in the United States District Court for the Eastern District of Virginia. Dr. Bajwa was charged with conspiracy to commit fraud against the United States (tax fraud), in violation of 18 USC § 371, and with a violation of the False Statement statute, 18 USC § 1001. The indictment was based on the false allegation that, for a period of approximately 20 years, Dr. Bajwa had wrongfully claimed deductions on his federal personal income tax for charitable contributions for

which he had allegedly been reimbursed. The False Statement charge was based on Dr. Bajwa's statement to agents from the Federal Bureau of Investigation on July 19, 2011, in which he denied that he had committed such a fraud.

- 11. Pursuant to an agreement with the government, Dr. Bajwa was permitted to plead guilty to a violation of the False Statement statute (framed differently than the charge in the indictment), and the government agreed to dismiss the first count of the indictment charging Dr. Bajwa with conspiracy.
- 12. Dr. Bajwa's guilty plea was expressly based on a very narrow set of facts, and did not include any admission that he had committed the tax fraud conspiracy that was the gravamen of the indictment. In connection with his plea, Dr. Bajwa admitted that, when he told federal law enforcement agents that a portion of his contribution to a certain U.S. charity had been sent to a women's college in Pakistan run by his uncle, he had failed to add that the reason that the money went to that nonprofit educational institution was that he had requested that it go there. As described in the Statement of Facts drafted by the government:

BAJWA told the investigators that some of the money that he donated to [the Society for International Help] was later distributed to charities managed by his relatives, but did not disclose to the investigators that the reason that some of the money was later so distributed was specifically because BAJWA earmarked his donation for that purpose

* * *

In fact, BAJWA's statement to the FBI was false and misleading because it suggested that BAJWA had no control over whether [the Society for International Help] used his money to fund a Pakistani college managed by his uncle when, as BAJWA well knew, of a \$10,000 donation that he made to [the Society for International Help] on September 18, 2008, \$5,000 was earmarked by him for a women's college in Pakistan that was managed by his uncle.

See Statement of Facts, *United States v. Bajwa*, Case No. 1:13-cr-402 (E.D. Va.), Document 55, attached hereto as Exhibit A.

- 13. Neither Dr. Bajwa nor his uncle affiliated with the women's college received any financial benefit as a result of the distribution of Dr. Bajwa's funds to the college, but the college benefited in that it relies upon charitable donations for much of its funding. This donation was only a small portion of many hundreds of thousands of dollars that Dr. Bajwa has donated to benefit healthcare and educational institutions in Pakistan.
- 14. At sentencing, notwithstanding its plea agreement, the government sought to prove, as "Relevant Conduct" under the United States Sentencing Guidelines, that Dr. Bajwa had, in fact, committed the tax fraud conspiracy charge that the government had agreed to dismiss. After a lengthy evidentiary hearing, the judge found that the government had failed to prove that allegation even by a preponderance of the evidence, and specifically stated that there was no evidence that Dr. Bajwa had participated in any criminal conspiracy.
- 15. After reviewing the record—including 150 letters submitted in support of Dr. Bajwa —the judge marveled at the support that Dr. Bajwa enjoyed in his community, and sentenced Dr. Bajwa to two years' probation with a fine (despite the government's request for imposition of a prison sentence):

I have a wide range of sentences that I can impose, and I look often not either to the defendant or the government, but to what the community believes that defendant represents to his community.

And it's absolutely clear that the community believes that Dr. Bajwa is a treasure, and that his continued activities in the community are of vital importance, not just to the mosque or to the hospital, but in the community as a whole for what he has done.

The judge "thank[ed] God for people like" Dr. Bajwa, and urged him to continue serving his community. *See* Partial Transcript of April 21, 2015 Hearing, *United States v. Bajwa*, Case No. 1:13-cr-402, attached hereto as Exhibit B.

Dr. Bajwa's notice to CMS and CMS' response

- 16. Following his sentencing, Dr. Bajwa notified CMS (through NGS) about the fact of his conviction. A member of Dr. Bajwa's staff first provided such notification telephonically on May 15, 2015. She was informed by the contractor that it was unnecessary to report the conviction, and the contractor was not willing to provide confirmation in writing. By letter dated May 21, 2015, Dr. Bajwa's staff person nevertheless provided written notice to CMS (through NGS). A copy of the letter is attached to this Complaint as Exhibit C.
- 17. In addition to notifying CMS, Dr. Bajwa notified and/or responded to regulatory and accrediting bodies involved in his practice of medicine, including but not limited to the New York State Office of Professional Medical Conduct, the New York Office of the Medicaid Inspector General, the Pennsylvania Board of Medical Licensing, and the American Board of Neurosurgery. None of those organizations took any action to prevent Dr. Bajwa from continuing to fully practice medicine.
- 18. By letter dated June 17, 2015, Dr. Bajwa received a written response to his staff member's May 21, 2015. CMS (through NGS) made clear that it had determined that it would take no action against Dr. Bajwa based upon his conviction:

After further review of the inquiry sent to our office, we have determined that there is no further action for Medicare to take. *Per your conversation with [an NGS representative], there was no action for you to take at the time.* The courts found there were no kickbacks involved; *therefore there is nothing further you or Medicare needs to do with this issue.* In the event there is a Provider Enrollment (PE) application submitted for this entity in the future[,] please include this letter for a reference. Otherwise we will keep this on file for informational purposes only.

(Emphasis added). A copy of this June 17, 2015, letter from NGS is attached hereto as Exhibit D.

Revocation of Dr. Bajwa's and SNY's Medicare billing privileges

- 19. Notwithstanding the unequivocal statements in the June 17, 2015, letter, in mid-October 2015, Dr. Bajwa's staff discovered that his Medicare billing privileges and those of SNY had been revoked. They discovered this only when billing that was submitted was rejected. On October 22, 2015, NGS notified Dr. Bajwa and SNY by telephone about the revocations. Dr. Bajwa was neither notified nor provided with any opportunity to respond before imposition of the revocation.
- 20. On October 26, 2015, Dr. Bajwa and SNY received letters dated October 16, 2015 (each with a postmark of October 19, 2015) notifying Dr. Bajwa and SNY that their Medicare billing privileges were revoked effective April 21, 2015 (the date of Dr. Bajwa's conviction). Copies of those letters are attached hereto as Exhibits E and F.
- 21. The letters each stated the same two bases for revocation: (1) Dr. Bajwa's April 21, 2015, conviction in the United States District Court for the Eastern District of one count of felony False Statements in violation of 18 USC §§ 1001(a)(2) (citing 42 CFR § 424.535(a)(3)(ii)(B)); and (2) Dr. Bajwa's alleged failure to report that conviction to NGS (citing 42 CFR § 424.535(a)(9)). The letter addressed to SNY noted, in addition, that Dr. Bajwa "was reflected as an Authorized Official and a 5% or more owner on [SNY's] Medicare Enrollment."
- 22. The regulation pursuant to which Dr. Bajwa's privileges were revoked permitted revocation only for a felony offense that the Secretary (or CMS) determined was "detrimental to the best interests of the Medicare program and its beneficiaries." Nevertheless, the October 16, 2015, revocation letters provided no indication of whether, how, when, or why NGS (or the Secretary or CMS) made that determination in this case.

The regulation applicable to Dr. Bajwa's conduct at issue permitted revocation only for felony offenses falling into four enumerated categories, none of which included a conviction under 18 U.S.C. § 1001.

- With respect to the first stated ground for revocation, NGS cited 42 CFR § 424.535(a)(3)(ii)(B), which permits revocation based on a conviction for "[f]inancial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes"—an unmistakable reference to the tax fraud conspiracy for which Dr. Bajwa was *not* convicted and which a United States District Judge had already found the government could not prove even by a preponderance of the evidence.
- 24. Following the receipt of notice of revocation, Dr. Bajwa (through counsel) directed the attention of CMS (through its attorneys) to the indisputable evidence that Dr. Bajwa had, in fact, provided the required notice of his conviction, and that the second stated ground for his revocation was clearly unsupportable.
- 25. In response to these communications, on or about November 16, 2015, NGS "reopen[ed] and revise[d]" its initial determination, and issued a revised notice of revocation (the "Revised Revocation Notice"). The Revised Revocation Notice (a copy of which is attached as Exhibit G) omitted the allegation of failure to report. Also, in an apparent concession that a conviction under 18 U.S.C. § 1001 does not fall under the "financial crime" category (or any of the other three categories in the regulation effective prior to February 2015), NGS now omitted citation to 42 CFR § 424.535(a)(3)(ii)(B), and instead relied upon a revised version of the regulation that was not in effect at the time of Dr. Bajwa's conduct (or even at the time that he entered his plea).

26. The Revised Revocation Notice also provided an ex post facto justification for the revocation of Dr. Bajwa's Medicare billing privileges based upon the government's description of the scope of its investigation—notwithstanding (and with no acknowledgement of) the court's finding that there was no evidence to support the government's assertion that Dr. Bajwa had committed any sort of criminal conspiracy. The letter noted NGS' belief that "the acknowledged false, fraudulent, misleading and material statement made by [Dr. Bajwa] to federal officials within the context of a very serious criminal investigation calls into question [Dr. Bajwa's] trustworthiness and veracity" and that revocation was therefore "necessary to ensure the integrity of Medicare trust funds." The letter did not allege, and could not truthfully allege, that Dr. Bajwa was made aware of the nature or seriousness of the criminal investigation at the time he spoke to federal officials. And the letter did not address the fact that Dr. Bajwa had been a provider in the Medicare system for nearly thirty years, and no question had ever been raised about the propriety and accuracy of any of his submissions for payment from Medicare during those years.

CMS claws back payments for services that Dr. Bajwa and his partners provided

- 27. Between April 2015 and October 2015, Dr. Bajwa and his partners continued to provide services to patients covered by Medicare.
- 28. During this period—and particularly after NGS' June 27, 2015 letter—Dr. Bajwa and his partners reasonably believed that they were entitled to provide services to patients covered by Medicare, and to seek appropriate reimbursement from Medicare for the provision of such services.

- 29. Indeed, during this period, Dr. Bajwa and his partners submitted numerous claims for reimbursement to Medicare for services they had provided, and Medicare continued to pay those valid and appropriate claims for reimbursement.
- 30. Nevertheless, following its notice to Dr. Bajwa that his billing privileges (and those of SNY) had been revoked, CMS clawed back from Dr. Bajwa and his then-partners \$277,000 in fees for services furnished by Dr. Bajwa.

Termination of Dr. Bajwa's billing privileges under Medicaid

- 31. Following Dr. Bajwa's conviction, by letter dated May 26, 2015, Dr. Bajwa reported the fact of (and details about) his conviction to the New York State Office of the Medicaid Inspector General ("OMIG"). (A copy of the letter from Dr. Bajwa's attorney to DOH is attached hereto as Exhibit H.)
- 32. By letter dated August 25, 2015, OMIG notified Dr. Bajwa that OMIG had determined that Dr. Bajwa would be censured as a result of his conviction. In that letter (a copy of which is attached hereto as Exhibit I), OMIG specifically stated that Dr. Bajwa was not terminated or excluded from the Medicaid program.
- 33. Following CMS' revocation of Dr. Bajwa's billing privileges, by letter dated August 31, 2016, the New York State Department of Health ("NYSDOH")notified Dr. Bajwa that, because Medicare had revoked Dr. Bajwa's billing privileges, NYSDOH was legally obligated to terminate Dr. Bajwa's privileges in the Medicaid program as well. A copy of that letter is attached hereto as Exhibit J.

Dr. Bajwa has presented his claim and has exhausted administrative proceedings

34. Dr. Bajwa made a timely request for reconsideration of CMS' Revised Revocation Notice by letter dated January 11, 2016. By letter dated April 11, 2016, NGS issued

an unfavorable determination in response to that request. (A copy of that reconsideration determination is attached hereto as Exhibit K.)

- 35. By letter dated May 12, 2016, Dr. Bajwa requested review by an ALJ of the Revised Revocation Notice and the reconsideration. In a decision dated November 10, 2016, the ALJ granted summary judgment in favor of CMS without holding a hearing, upholding the Revised Revocation Notice and the redetermination. (A copy of the ALJ's decision is attached hereto as Exhibit L.)
- 36. On or about December 20, 2016, Dr. Bajwa filed an appeal to the DAB. On June 22, 2017, the DAB finally issued its ruling in which it upheld the decision of the ALJ. (A copy of the DAB decision is attached hereto as Exhibit M.)

Violations of Due Process and other laws in revocation of Dr. Bajwa's billing privileges

- a. CMS' illegal retroactive application of a revised regulation
- 37. The conduct that formed the basis for Dr. Bajwa's criminal conviction occurred on July 19, 2011.
- 38. In revoking Dr. Bajwa's Medicare billing privileges, CMS illegally retroactively applied a regulation that did not become effective until February 2015—over three years after Dr. Bajwa's conduct that was the subject of the revocation.
- 39. The regulations in effect in July 2011 provided that a provider or supplier could have its Medicare billing number revoked based on a felony conviction only if the felony fell into one of four enumerated categories, none of which applied to Dr. Bajwa. *See* 42 C.F.R. § 424.535(a)(3)(i) (2013), copy attached at Exhibit N (the "2011 Regulation").
- 40. In 2013, CMS began the process of revising the regulations pertaining to revocation of Medicare privileges based on a felony conviction. In doing so, CMS ignored the

protests of numerous public comments, and reserved to itself unfettered discretion to determine whether a felony conviction is "detrimental to the best interests of the program or program beneficiaries" without providing any indication of what factors it would consider in making that determination.

- 41. During the process of amending the regulation, CMS made clear that one purpose of the amendment of this regulation was to permit CMS to revoke the Medicare billing privileges of a provider based upon offenses other than those falling within the four enumerated categories in the 2011 Regulation. CMS itself made clear its own view that, under the 2011 Regulation, CMS' revocation authority for felony convictions had been limited to cases involving offenses that fell within the four enumerated categories.
- 42. In its proposed rule, CMS made clear its intent to expand significantly the set of circumstances under which it could exercise its revocation authority. The proposed rule stated that "[t]he most significant of [the proposed] revisions include: . . . *expanding the instances* in which a felony conviction can serve as a basis for denial or revocation of a provider or supplier's enrollment." 78 Fed. Reg. at 25013 (emphasis added). CMS itself explained that the proposed rule sought to change 42 C.F.R. § 424.535(a)(3) as follows:

To modify the list of felonies in each section such that any felony conviction—including guilty pleas and adjudicated pretrial diversions—that we have determined to be detrimental to the best interests of the Medicare program and its beneficiaries would constitute a basis for denial or revocation. This would give us the discretion to deny or revoke enrollment based on any felony conviction that we believe to be detrimental to the best interests of Medicare and its beneficiaries. There are several reasons for this change:

++ In light of the very serious nature of any felony conviction, we believe it is unwise to restrict our authority in § 424.530(a)(3)(i) and § 424.535(a)(3)(i) to the categories of felonies identified in (a)(3)(i); this is especially true considering that the types of felony offenses often vary from state to state. . . .

++ The current list of felonies in § 424.530(a)(3) and § 424.535(a)(3) includes many felonies but *does not encompass all felonies*. In order to allow us discretion to deny or revoke enrollment *based on any felony conviction* that we believe is detrimental to the Medicare program or its beneficiaries, *we propose to eliminate the enumerated list of felonies* and instead provide that enrollment may be denied or revoked based upon any such felony conviction.

78 Fed. Reg. at 25021-22 (emphasis supplied).

43. In connection with the publication of the final rule in December 2014, CMS made similar statements making clear that its intent in a mending the regulation was not somehow clarifying existing authority, but expanding CMS' revocation authority. The Secretary noted that she had "proposed several changes to §§ 424.530(a)(3)(i) and 424.535(a)(3)(i)," the first of which was

to modify the list of felonies in each section such that any felony conviction that we determine to be detrimental to the best interests of the Medicare program and its beneficiaries would constitute a basis for denial or revocation. We stated that considering the very serious nature of any felony conviction, our authority in §§ 424.530(a)(3)(i) and 424.535(a)(3)(i) should not be restricted to the categories of felonies identified in (a)(3)(i); this was especially true considering that the types of felony offenses often vary from state to state.

79 Fed. Reg. at 72509-10 (emphasis added). *See also* 79 Fed. Reg. at 72510 ("Several commenters disagreed with CMS' proposed expansion of §§ 424.530(a)(3) and 424.535(a)(3) to include all felonies"); 79 Fed. Reg. at 72512 (reporting commenter's statement regarding CMS "proposing its expansion of §§ 424.530(a)(3) and 424.535(a)(3) to include all felonies"); *id*. (reporting commentator concern regarding "the expansion of the felonies encompassed by § 424.535(a)(3)").

- 44. As amended, 42 CFR § 424.535(a)(3) states:
- (a) Reasons for revocation. CMS may revoke a currently enrolled provider or supplier's Medicare billing privileges and any corresponding provider agreement or supplier agreement for the following reasons: . . .

(3) Felonies. (i) The provider, supplier, or any owner or managing employee of the provider or supplier, was, within the preceding 10 years, convicted . . . of a Federal or State felony offense that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries.

The proposed rule was finalized in December 2014 and made effective on February 3, 2015. See 78 Fed. Reg. 25013 (April 29, 2013) (proposed rule); 79 Fed. Reg. 72500 (December 5, 2014) (final rule). A copy of the revised regulation (the "February 2015 Regulation") is attached as Exhibit O.

- 45. Dr. Bajwa committed the conduct that was the basis for his conviction in July 2011 during his interview with FBI agents. He entered his guilty plea in November 2014, and he was sentenced in April 2015.
- 46. CMS has argued (and the ALJ and DAB have agreed) that the February 2015 Regulation was not applied retroactively because its effective date preceded the entry of Dr. Bajwa's judgment of conviction on the date of his sentencing in April 2015. But neither the 2013 proposal leading to the February 2015 Regulation nor the 2014 final rule proposed to, or otherwise put the public on notice, that the proposed expansion of grounds for which a felony conviction could serve as the basis for a revocation of billing privileges would apply to conduct that occurred prior to the effective date of the new rule.
- 47. The question of whether the February 2015 Regulation was applied retroactively cannot depend solely on the date of entry of conviction. If the fact of conviction were the material issue in determining whether Dr. Bajwa was to be revoked, *every* felony conviction would be deemed detrimental and would be a basis for revocation. Even CMS does not read its regulation that way.
- 48. Rather, CMS must make its "detrimental" determination based on the conduct underlying the conviction. This makes perfect sense: The question of whether a provider's

continued participation will harm the program or its beneficiaries depends on what kind of bad conduct the provider has committed. Because a conviction can occur only where there is evidence of guilt beyond a reasonable doubt, the conviction serves to ensure that CMS will only act upon bad conduct that the provider has actually committed.

- 49. Here, CMS unquestionably based its determination on an examination of Dr. Bajwa's conduct and not on the mere fact of his conviction. That is apparent from the Revised Revocation Notice, which references the specific facts underlying Dr. Bajwa's conviction as the basis for the determination to revoke his privileges. If the determination had been based solely on the conviction, there would have been no need to reference those facts.
- on whether individuals subject to its enforcement had the opportunity to conform their conduct to the new regulation after its effective date. Here, Dr. Bajwa had made the statements and omissions in question years before the effective date of the February 2015 Regulation (and, moreover, had entered his guilty plea in November 2014, several months prior to that effective date). The February 2015 Regulation is properly read as applying the expansion of grounds upon which a felony conviction can serve as the basis for a revocation prospectively—that is, only to conduct occurring on or after the effective date of the February 2015 Regulation. Therefore, the NGS revocation determination upheld by the DAB resulted from the improper application of the the February 2015 regulation, which does not apply to conduct preceding its effective date. This reading is compelled by longstanding Supreme Court precedent stating that agencies are required to follow their regulations.
- 51. Even if February 2015 Regulation were properly read by its terms as purporting to allow the revocation of billing privileges based on conduct preceding the effective date of the

regulation, its application to Dr. Bajwa's 2011 conduct violates the law. The Supreme Court has held that agencies do not have the authority to apply their regulations retroactively absent specific Congressional authorization. *Bowen v. Georgetown University Hospital*, 488 U.S. 204 (1988). And, in section 903(a) of the Medicare Modernization Act of 2003, Pub. L. No. 108-73 (entitled "No retroactive application of substantive changes"), Congress specifically prohibited the Secretary from giving retroactive effect to substantive changes in her regulations (unless the Secretary determined at the time of the rulemaking that retroactive effect was necessary to comply with a statute or was in the public interest). The Secretary made neither determination in connection with the February 2015 Regulation at issue here, and the retroactive application of the February 2015 Regulation is thus contrary to law.

52. In this case, CMS clearly perceived that it had no choice but to seek the illegal retroactive application of the February 2015 Regulation to Dr. Bajwa's conduct. The original, October 16, 2015 revocation notice from NGS cited 42 C.F.R. § 424.535(a)(3)(ii)(B) ("Financial crimes") as the basis for revoking Dr. Bajwa's Medicare billing privileges, along with § 424.535(a)(9) ("Failure to report"). Neither of these bases were sufficient. As a factual matter, Dr. Bajwa had, in fact, reported the fact of his conviction. And, as one of HHS' ALJs recently held (*see In re Subramanya K. Prasad, M.D.*, No. C-16-23 Decision No. CR4522 (February 5, 2016) (attached as Exhibit P)), a conviction pursuant to 18 U.S.C. § 1001 does not fall within the four enumerated categories of felonies listed in the 2011 Regulation. Indeed, in that administrative appeal, CMS did not contest that legal ruling.

- b. CMS' failure to provide any opportunity to respond prior to revocation
- 53. Because Dr. Bajwa's billing privileges in the Medicare program could be revoked only for cause (based upon the 2011 Regulation), Dr. Bajwa held a Constitutionally protected property interest in his continued participation in the Medicare program.
- 54. Here, Dr. Bajwa had no notice of the revocation of his Medicare billing privileges until after it had been imposed.
- 55. CMS thus deprived Dr. Bajwa of the Constitutional guarantees of due process in the form of notice and a meaningful opportunity to respond before the imposition of the revocation.
- 56. In the related context of exclusion, CMS' regulations specifically provide (with some narrow exceptions) that it will provide notice and a meaningful opportunity to be heard prior to the imposition of exclusion. *See*, *e.g.*, 42 C.F.R. § 1001.2001(a) (providing for issuance of "notice of intent to exclude" and granting 30 days to provide "documentary evidence and written argument in response" prior to imposition of exclusion under certain authorities). In the rulemaking period for that regulation, the Office of Inspector General for the Department of Health and Human Services explained that the opportunity to respond was essential as a matter of Constitutional right:

As we stated in the preamble to the proposed regulations, case law makes clear that due process does not require a *hearing* prior to the imposition of an exclusion from Medicare or State health care programs (*see Mathews v. Eldridge*, 424 U.S. 319 (1976); [citation omitted]. *When an agency exercises discretionary authority, due process is satisfied so long as the affected party is given "notice and an opportunity to respond * * * (t)he opportunity to present reasons, either in person or in writing, why proposed action should not be taken" (see Cleveland Bd. of Education v. Loudermill, 470 U.S. 532, 105 S.Ct. 1487, 1495 (1985)). This final rule reflects this constitutional principle.*

57 Fed. Reg. at 3319 (emphasis added).

- c. The February 2015 Regulation is constitutionally deficient and arbitrary and capricious
- 57. Even if the current regulations were applicable, they are Constitutionally deficient and arbitrary and capricious.
- 58. As a matter of due process, the February 2015 Regulation under which NGS revoked Dr. Bajwa's Medicare privileges fails to provide "fair notice" to providers and suppliers such as Dr. Bajwa of what conduct will result in revocation of Medicare billing privileges.
- 59. Section 1842(h)(8) of the Social Security Act (codified at Title 42, U.S. Code § 1395u(h)(8)) states that the Secretary "may refuse to enter into an agreement with a physician or supplier under this subsection, or may terminate or refuse to renew such agreement, in the event that such physician or supplier has been convicted of a felony under Federal or State law for an offense which the Secretary determines is detrimental to the best interests of the program or program beneficiaries." (emphasis added)
- 60. Nowhere in the United States Code has Congress provided any definition or other guidance for the Secretary's determination of whether an offense is "detrimental to the best interests of the program or program beneficiaries" as that phrase is used in the February 2015 Regulation.
- 61. Neither the February 2015 Regulation nor any other CMS regulation provide a definition of what is "detrimental to the best interests of the Medicare program and its beneficiaries" or any guidance on how CMS is to make that determination.
- 62. Because neither Congress nor CMS provided any definition of what is "detrimental to the best interests of the Medicare program and its beneficiaries" or any guidelines for such determinations, this statute and regulation fail to provide "fair notice" to Dr. Bajwa and

other providers and suppliers of what felony convictions will result in revocation of Medicare billing privileges.

- 63. The lack of fair notice to providers and suppliers is particularly egregious where, as here, CMS imposes a revocation retroactive to the date of a provider's conviction, and then claws back payments it has made for services provided since the date of conviction. According to 42 C.F.R. § 424.535(g), the effective date of a revocation of billing privileges is the date of the felony conviction, and *not* the date of the notice informing the provider or supplier that has revoked its billing privileges. Under the February 2015 Regulation, a physician or other practitioner may (but will not necessarily) have its billing privileges revoked for a felony conviction, but the basis for doing so— "detrimental to the best interests of the Medicare program and its beneficiaries"—is amorphous, undefined and unaccompanied by any guidance. For that reason, a physician will not know at the time of his conviction whether he will in fact have his billing privileges revoked.
- 64. The result of this ambiguity is that a physician or other practitioner who is convicted of a felony may reasonably choose to furnish services covered by Medicare between the time of conviction and the date of the notice of revocation for which he ultimately will not be paid. Even worse, as was the case with Dr. Bajwa, a physician may provide services and receive reimbursement from Medicare but be forced to return those payments to CMS after receiving notice of revocation months later. If a determination to revoke were made promptly, the situation might not be as bad (leaving aside the lack of fair notice and other issues) but there is no limit on how long CMS' contractor may wait to make a determination to revoke. This means that a physician may provide services for months for which he ultimately will not be paid.

NGS within 30 days of his conviction, but his billing privileges were not revoked until October 16, 2015 (and he did not receive notice until October 22, 2015). During this period of almost six months, Dr. Bajwa and the other physicians at SNY continued to treat Medicare patients—at least in part in reliance on NGS' letter dated June 27, 2015 that Dr. Bajwa's Medicare billing privileges would *not* be revoked. Nevertheless, they were subsequently forced to give back the \$277,000 in payments that they received for services that were necessary and appropriate and for which billing claims were unquestionably proper.

COUNT ONE (FAILURE TO COMPLY WITH REGULATION)

- 66. Dr. Bajwa repeats the allegations contained in paragraphs 1 through 65 as if set forth here in full.
- 67. On its face, the February 2015 Regulation does not apply to conduct that precedes its February 2015 effective date, and it therefore could not be a valid basis for NGS' determination to revoke Dr. Bajwa's Medicare billing privileges.

COUNT TWO <u>VIOLATION OF THE ADMINISTRATIVE PROCEDURE ACT</u> (PROCEDURAL INVALIDITY OF REGULATION PERMITTING CLAWBACK)

- 68. Dr. Bajwa repeats the allegations contained in paragraphs 1 through 67 as if set forth here in full.
- 69. During the process in which CMS revised its regulation to provide that revocation would be retroactive to the date of conviction, CMS failed to give notice that it would seek clawback of fees paid to providers for treatment of patients during the period between the date of conviction and the time at which CMS notified the provider of the revocation.

70. The failure of CMS to provide such notice renders the portion of the regulations making revocations retroactive to the date of conviction procedurally invalid under the Administrative Procedure Act (the "APA"), and section 1872 of the Social Security Act, 42 U.S.C. § 1395hh.

COUNT THREE VIOLATION OF THE ADMINISTRATIVE PROCEDURE ACT AND THE SOCIAL SECURITY ACT (PROCEDURALLY INVALID REGULATION)

- 71. Dr. Bajwa repeats the allegations contained in paragraphs 1 through 70 as if set forth here in full.
- 72. Neither the proposed rule nor the final rule for the February 2015 Regulation gave notice that the February 2015 Regulation would apply to conduct that preceded the effective date of that revised regulation.
- 73. The failure to provide such notice renders the February 2015 Regulation procedurally invalid under the rulemaking provisions of the APA, and section 1872 of the Social Security Act, 42 U.S.C. § 1395hh. In addition, the failure to give any explanation in the final rule why the regulation should apply to conduct preceding the effective date of the regulation renders the February 2015 Regulation arbitrary and capricious and invalid under the APA.

COUNT FOUR VIOLATION OF THE ADMINISTRATIVE PROCEDURE ACT AND THE SOCIAL SECURITY ACT (SUBSTANTIVELY INVALID REGULATION)

- 74. Dr. Bajwa repeats the allegations contained in paragraphs 1 through 73 as if set forth here in full.
- 75. As amended by section 903(a) of the Medicare Modernization Act of 2003, Pub.L. No. 108-73 (entitled "No retroactive application of substantive changes"), the Social Security

Act specifically prohibits the Secretary from giving retroactive effect to substantive changes in regulations unless the Secretary determined at the time of the rulemaking that retroactive application was necessary to comply with statutory requirements, or failure to apply the change retroactively would be contrary to the public. *See* 42 U.S.C. § 1395hh(e)(1)(A).

- 76. The amendment that resulted in the February 2015 Regulation made a substantive change by abandoning the requirement that a provider's felony conviction fall within four enumerated categories, and instead providing the Secretary with broad discretion to determine that a felony conviction should result in revocation.
- 77. The Secretary did not make a determination at the time of rulemaking relating to the February 2015 Regulation that retroactive effect was necessary to comply with a statute or was in the public interest.
- 78. Any retroactive application of the February 2015 Regulation to conduct that occurred before the effective date of the regulation is therefore contrary to law, and violates the APA and the Social Security Act, as amended by the Medicare Modernization Act, and applicable Supreme Court precedents.

COUNT FIVE VIOLATION OF THE DUE PROCESS CLAUSE OF THE FIFTH AMENDMENT TO THE UNITED STATES CONSTITUTION (UNCONSTITUTIONAL RETROACTIVE APPLICATION OF REGULATION)

- 79. Dr. Bajwa repeats the allegations contained in paragraphs 1 through 78 as if set forth here in full.
- 80. If the February 2015 Regulation is read to apply by its terms to conduct that preceded its effective date, the retroactive application of that statute to Dr. Bajwa's 2011 conduct as a basis for his revocation violated Dr. Bajwa's right to Due Process under the Fifth Amendment to the United States Constitution.

COUNT SIX <u>VIOLATIONS OF THE DUE PROCESS CLAUSE OF THE</u> <u>FIFTH AMENDMENT TO THE UNITED STATES CONSTITUTION</u> (LACK OF NOTICE AND MEANINGFUL OPPORTUNITY TO RESPOND)

- 81. Dr. Bajwa repeats the allegations contained in paragraphs 1 through 80 as if set forth here in full.
- 82. The revocation of Dr. Bajwa's Medicare billing privileges without prior notice and a meaningful opportunity to respond has resulted in a violation of Dr. Bajwa's right to Due Process under the Fifth Amendment to the United States Constitution.

COUNT SEVEN VIOLATION OF THE APA AND THE DUE PROCESS CLAUSE OF THE FIFTH AMENDMENT TO THE UNITED STATES CONSTITUTION (LACK OF FAIR NOTICE)

- 83. Dr. Bajwa repeats the allegations contained in paragraphs 1 through 82 as if set forth here in full.
- 84. The revocation of Dr. Bajwa's Medicare billing privileges under a statute and regulation that fail to provide "fair notice" to Dr. Bajwa has resulted in a violation of Dr. Bajwa's right to Due Process under the Fifth Amendment to the United States Constitution.
- 85. In addition, the lack of "fair notice" in the February 2015 Regulation renders that regulation arbitrary and capricious and therefore in violation of the APA.

COUNT EIGHT VIOLATION OF THE ADMINISTRATIVE PROCEDURE ACT (DETERMINATION TO REVOKE DR. BAJWA'S PRIVILEGES)

- 86. Dr. Bajwa repeats the allegations contained in paragraphs 1 through 85 as if set forth here in full.
- 87. The decision of CMS to revoke Dr. Bajwa's Medicare billing privileges was arbitrary and capricious and/or an abuse of discretion.

- 88. As documented in its June 27, 2015, letter, CMS determined that Dr. Bajwa's conviction did not require any action—in particular, that it did not require revocation of Dr. Bajwa's Medicare billing privileges. In order to reach that conclusion, CMS must implicitly have also concluded that the crime for which Dr. Bajwa was convicted was not one that the Secretary had determined is detrimental to the best interests of the program or program beneficiaries.
- 89. NGS included in its initial notice of revocation the false allegation that Dr. Bajwa failed to report his criminal conviction, as well as the false statement that Dr. Bajwa had been convicted of a financial crime.
- 90. CMS' and NGS' changing position on revocation, and the gradually evolving justification for that determination, clearly show the arbitrary and capricious quality of the decision-making on Dr. Bajwa's revocation.
- 91. Moreover, given the comments of the District Judge who sentenced Dr. Bajwa, urging him to continue his highly skilled and compassionate treatment of patients in his community, CMS' supposed determination that Dr. Bajwa's participation in the Medicare program would be detrimental to the best interests of the program and its beneficiaries was arbitrary and capricious.
- 92. Second, the decision to bar Dr. Bajwa from re-enrollment in the Medicare program for three years from the date on which he received notice of revocation is arbitrary and capricious, an abuse of discretion, and otherwise contrary to law in that CMS has not (and cannot) provide any justification for imposing the maximum bar period on Dr. Bajwa.
- 93. Third, by permitting NGS—rather than CMS—make the determination that Dr. Bajwa's conviction was one for which he could be revoked, CMS acted contrary to the plain language of the February 2015 Regulation, which CMS is required to follow.

- 94. Fourth, because Dr. Bajwa's revocation was effective April 2015 but the reenrollment bar runs from the time when he was notified of the revocation, he is effectively kept out of the Medicare program for a period of far more than three years. Given that the three-year period is the maximum period for a reenrollment bar, it is contrary to law to permit CMS to keep Dr. Bajwa out of Medicare for a period of time greater than three years.
- 95. Fifth, CMS' clawback of fees for medically necessary and appropriate services that Dr. Bajwa provided between April 21, 2015, and October 16, 2015 was arbitrary and capricious and contrary to law.
- 96. Although Dr. Bajwa timely reported the fact of his criminal conviction to CMS (through its contractor), and was led to believe by NGS that his billing privileges would not be revoked, NGS waited until October—nearly six months after the conviction—to revoke his billing privileges.
- 97. During those months, Dr. Bajwa continued to deliver medically necessary and appropriate treatment to patients covered by Medicare based on his understanding that his criminal conviction had not altered the status of his participation in the Medicare program. This understanding was fostered by the letter from NGS stating that there was no need for further action based upon his criminal conviction, and by Medicare's continued payment of Dr. Bajwa's claims for services during that period.
- 98. Nevertheless, after revoking his Medicare billing privileges in October, CMS demanded (and received) the return of \$277,000 that had been paid for services that Dr. Bajwa had provided. Dr. Bajwa thus ultimately provided those services without receiving any payment.
- 99. The clawback of these funds was without prior notice or a meaningful opportunity to be heard, and was otherwise arbitrary and capricious and/or contrary to law.

WHEREFORE, Dr. Bajwa requests the following relief:

- (a) Judgment finding that, as properly read, the February 2015 Regulation did not apply to Dr. Bajwa's 2011 conduct that occurred prior to the effective date of the February 2015 Regulation, and that Dr. Bajwa therefore could not have his privileges revoked pursuant to the February 2015 Regulation;
- (b) Alternatively, judgment finding that the February 2015 Regulation is procedurally and/or substantively invalid under the APA and the Social Security Act;
- (c) Alternatively, judgment finding that the revocation of Dr. Bajwa's billing privileges was the result of an illegal retroactive application of a regulation that was not in effect during Dr. Bajwa's conduct at issue;
- (d) Judgment that the determination to revoke Dr. Bajwa's billing privileges was contrary to the requirements of the Due Process Clause of the Constitution and was otherwise arbitrary, capricious, and contrary to law and regulation;
 - (e) An order requiring Dr. Bajwa's Medicare billing privileges be restored;
- (f) An order requiring that the overpayment created due to the retroactive denial of Medicare services he furnished be rescinded and that all monies recouped from SNY or Dr. Bajwa as a result of such denial be repaid immediately; and

(g) Such other and further relief as the Court may deem just and appropriate.

Dated: July 19, 2017 HARRIS, ST. LAURENT & CHAUDHRY LLP

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